Appendix 3.8.4 on surveillance and monitoring systems for BSE

The Bureau noted that the *ad hoc* Group had examined comments on the appendix submitted by Member Countries in making its recommendations.

APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

Surveillance for bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

1) cattle not exposed to the infective agent;

2) cattle exposed but not infected;

3) infected cattle, which may lie within one of three stages in the progress of BSE:

   a) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

   b) some will progress to a stage at which BSE is detectable by testing before clinical signs ~~of disease~~ appear;

   c) the smallest number will show clinical signs ~~of disease~~.

A surveillance programme~~s~~ on its own cannot guarantee BSE status and should be determined by, and be commensurate with, the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While Surveillance should focus on the sub-population containing cattle displaying clinical signs consistent with BSE as described in Article 3.8.4.2.this sub-population Where it is difficult to access all cattle displaying such clinical signs, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate assessment picture of the BSE situation

in the country or zone. A surveillance strategy programme may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below. Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in In addition, the first two sub-populations should be addressed by the surveillance can be complemented by sampling of normal cattle over 30 months of age at slaughter according to Article 3.8.4.4. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000. Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Terrestrial Manual*. For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health.

Article 3.8.4.2.

Examination of cattle displaying clinical signs consistent with bovine spongiform encephalopathy

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying ~~with compatible~~ clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle; a mortality rate not exceeding one percent per year in adult cattle; and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle. In countries where these assumptions do not apply, a different sampling rate needs to be used to reach the same conclusions.

As this sampling is not random, and as the mortality rate and prevalence of CNS signs within dying cattle may vary, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction. This table should only be employed as a general guideline. Sampling in excess of the number indicated, ideally extending towards all cattle over 30 months of age showing clinical signs consistent with BSE, would give greater confidence in the outcome and is to be encouraged. In those cases, where there is a shortfall in the number of samples required under this article, the difference may be made up by any combination of samples defined under Articles 3.8.4.3 and 3.8.4.4.

Table 1. ***Minimum number of annual investigations of cattle showing clinical signs consistent with BSE required for effective surveillance according to the total cattle population over 30 months of age.***

Total cattle population over 30 months of age	Minimum number of samples to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

[Note: Need to develop numbers for populations lower than 500,000.]

Article 3.8.4.3.

Examination of targeted cattle displaying clinical signs not necessarily indicative of bovine spongiform encephalopathy

Cattle over 30 months of age that have died or have been killed for reasons other than routine slaughter should be examined. This population will include cattle which have died on farm or in transit, cattle which are unable to rise or to walk without assistance, ~~'fallen stock'~~, and ~~stock~~ cattle sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being ~~compatible~~ consistent with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE. Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 100 or more animals in this category in terms of its ability to detect BSE within an infected cattle population.

This multiplication factor of 100 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2.

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter of cattle over 30 months of age is a means of monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Empirical evidence indicates that surveillance conducted on one clinical suspect

from Article 3.8.4.2. is equivalent to that conducted on 5,000 to 10,000 animals in this category in terms of its ability to detect BSE within an infected cattle population.

This multiplication factor of 5,000 to 10,000 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2 and a multiplication factor of 50 to 100 applied regarding any shortfall in the sample numbers specified in Article 3.8.4.3.

Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.